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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,868	12/05/2000	Kenneth C. Gross	0066.99	9165

7590 08/27/2002

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ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 08/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/701,868 Examiner Cynthia Collins	GROSS ET AL. Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06 June 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) 5-7,9-11,19-21,23-25 and 27-32 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-4,8, 12-18, 22 and 26 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-18 and 22-26, and the nucleic acid of SEQ ID NO:4 encoding the amino acid sequence of SEQ ID NO:11 (also designated TBG4 and Accession No. AFO 20390), in Paper No. 5 is acknowledged. Regarding restriction of the nucleotide and amino acid sequences, the traversal is on the ground(s) that Markush practice as set forth in paragraph 803.02 of the MPEP states that "should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended". The traversal is also on the grounds that no serious burden would be placed on the examiner to search all of the claims because the different groups of invention all claim subject matter that is closely related.

This is not found persuasive because no requirement for a species election was set forth in the office action mailed June 6, 2002. The office action stated that restriction to a single nucleotide or amino acid sequence was required under 35 U.S.C. 121 and 372.

This is also not found persuasive because while the search of Groups I-VI may overlap, their searches are not coextensive of each other. In this particular instance, a search of Group II is not coextensive with a search of Group I, since Group II requires a search for an isolated β -galactosidase II polypeptide not claimed in Group I. A search of Group III is not coextensive with a search of Group I, since Group III requires a search for an isolated polypeptide comprising an epitope-bearing portion of the β -galactosidase II protein not claimed in Group I. A search of Group IV is not coextensive with a search of Group I, since Group IV requires a search for an antibody not claimed in Group I. A search of Group V is not coextensive with a search of

Group I, since Group V requires a search for a method of modifying cell wall metabolism in a plant not claimed in Group I. A search of Group VI is not coextensive with a search of Group I, since Group VI requires a search for a method of modifying β -galactosidase II gene expression not claimed in Group I.

Furthermore, because claims 5-7, 9-11 and 23-25 are directed to nonelected nucleic acid sequences, they are withdrawn from consideration as being directed to nonelected inventions. Claims 19-21 and 27-32 are also withdrawn from consideration as being directed to nonelected inventions. Additionally, all nonelected nucleotide and amino acid sequences are withdrawn from consideration as being directed to nonelected inventions. Claims 1-4, 8, 12-18, 22 and 26 are examined on the merits in the instant office action.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

The drawings are objected to by the Draftsperson as informal for the reasons indicated on Form PTO 948. Applicant is advised that, upon correction of the drawings, amendment of the brief description of the drawings and of the claims that refer to Figures 2 and 3 will also be necessary.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

Claims 1, 2, 22 and 26 are objected to because they recite the sequences of nonelected inventions. Appropriate correction is required.

Claim 18 is objected to for omitting an article before "β-galactosidase II polypeptide". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8, 12-18, 22 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the cDNA clone claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the cDNA clone in GenBank Accession No. AF020390 is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same cDNA clone in each occurrence and it is not apparent if such a cDNA clone is readily available to the public. It is noted that applicants have deposited the cDNA clone under the depository accession number: GenBank Accession No. AF02039, but there is no indication in the specification as to public availability. If the deposit of this cDNA is made under the terms of the Budapest Treaty, then an

affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that GenBank Accession No. AF02039 will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

For each deposit made pursuant to these regulations, the specification shall be amended to contain (see M.P.E.P. § 1.809):

- (1) The accession number for the deposit;
- (2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 8, 12-18, 22 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4 and 22 are indefinite in the recitation of "polypeptide having the amino acid sequence at about positions 24-274". What amino acids does the mature β -galactosidase II comprise? The metes and bounds of "about positions 24-274" are unclear. Further, the SEQ ID NOS: are not positions.

Claims 3 and 4 are indefinite in the use of parentheses. The relationship between Figure 2 and SEQ ID NO:4 is unclear. It is suggested that the claims be amended to recite SEQ ID NO:4.

Claim 12 is indefinite in the recitation of "hybridizes under stringent hybridization conditions". It is unclear what conditions would yield the claimed nucleic acid molecules, as those of skill in the art define stringent hybridization conditions differently. It is suggested that the claims be amended to recite specific hybridization conditions.

Claim 12 is indefinite in the recitation of the indefinite article "a" before "nucleotide sequence in (a), (b), or (c) of claim 1". It is suggested that the claim be amended to recite the definite article "the" before "nucleotide sequence in (a), (b), or (c) of claim 1".

Claim 13 is indefinite in the recitation of "encodes the amino acid sequence an epitope bearing portion of a β -galactosidase II polypeptide". It is unclear what "portion" refers to - a portion of the epitope? the entire epitope itself? It is also unclear whether the nucleic acid encodes any amino acids that are not a part of the epitope.

Claim 13 is indefinite in the recitation of the indefinite article "an" before "amino acid sequence in (a), (b), or (c) of claim 1". It is suggested that the claim be amended to recite the definite article "the" before "amino acid sequence in (a), (b), or (c) of claim 1".

Claim 13 is indefinite in the recitation of "an amino acid sequence in (a), (b), or (c) of claim 1", as part (c) of claim 1 is directed to a nucleotide sequence. It is suggested that the claim be amended to recite that the amino acid sequence is encoded by the nucleotide sequence in (a), (b), or (c) of claim 1.

Claim 14 is indefinite in the recitation of the indefinite article "an" before "isolated nucleic acid molecule of claim 1". It is suggested that the claim be amended to recite the definite article "the" before "isolated nucleic acid molecule of claim 1".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 12-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ross et al. (1994, Plant Physiology, Vol. 106, pages 521-528).

The claims are drawn to isolated nucleic acid molecules complementary to any nucleotide sequence in (a) or (b) of claim 1, and to a recombinant vector and host cell comprising said isolated nucleic acid molecules. The claims are also drawn to methods for making a recombinant vector and host cell, and to a method for producing a β -galactosidase II polypeptide.

Ross et al. teach an isolated nucleic acid molecule complementary to any nucleotide sequence in (a) or (b) of claim 1 (page 525 Figure 3), and a recombinant vector and host cell comprising said isolated nucleic acid molecule (page 523 column 1, second full paragraph). Ross et al. also teach a method for making a recombinant vector and host cell, and a method for producing a β -galactosidase II polypeptide (Id. and page 524 column 2, first full paragraph). Although the sequence taught by Ross et al. is not fully complementary to a sequence encoding the β -galactosidase II polypeptide of SEQ ID NO:11, the claims are not so limited. It is suggested that the claims be amended to recite "fully complementary" to overcome the rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 8, 12-18, 22 and 26 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims are drawn to isolated nucleic acid molecules encoding β -galactosidase II polypeptides, and to methods of using said isolated nucleic acid molecules. Although the claims recite that the isolated nucleic acid molecules have structural features in common with the nucleotide sequence of SEQ ID NO:4 or encode polypeptides having structural features in common with the amino acid sequence of SEQ ID NO:11, the claims do not recite any function

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for the polypeptide encoded by the claimed polynucleotides, and the claims encompass degenerate DNA which cannot be used for hybridization.

Claims 1-4, 8, 12-18, 22 and 26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
August 26, 2002


PHUONG T. BUI
PRIMARY EXAMINER 8/26/02